

Applicant: Patrice Flaherty
Application No: 10/630,402
Filing Date: 07/30/2003
Attorney Docket No: 1066

REMARKS

Claims 1-23 are pending herein.

Claims 12-23 were withdrawn from consideration.

Claims 24-32 have been added.

Claims 1-11 were rejected.

Claims 1, 5, 7 and 10 are currently amended.

The amendments to 5 and 10 are unrelated to the statutory requirements for patentability of claims 5 and 10.

The addition of claims 24-32 are unrelated to the statutory requirements for patentability of claims 1-23.

Election/Restrictions

Restriction was made to the following patentably distinct species of the claimed invention: Species I: embodiment disclosed in Figure 1; Species II: embodiment disclosed in Figure 2; Species III: embodiment disclosed in Figure 4; and Species IV: embodiment disclosed in Figure 6. Restriction was further made to Species A: embodiment disclosed in Figure 6A and Species B: embodiment disclosed in Figure 6B.

Under the provisions of 35 U.S.C. 121, applicant was required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant: Patrice Flaherty
Application No: 10/630,402
Filing Date: 07/30/2003
Attorney Docket No: 1066

Accordingly, applicant elects without traverse to prosecute claims 1-11 and new claims 24-32, which correspond to Species I, the embodiment disclosed in Figure 1, and Species B, the embodiment disclosed in Figure 6B.

Specification

The Abstract of the Disclosure was objected to because of excessive length. Correction was required.

It will be noted that the Abstract of the Disclosure has been amended to reduce the length of the Abstract. Reconsideration is therefore respectfully solicited.

It was stated that the use of the trademark SaranWrap has been used in the application and should be capitalized wherever it appears and be accompanied by the generic terminology.

It will be noted that the specification has been amended to delete reference to SaranWrap. Reconsideration is therefore respectfully solicited.

Claim Rejections Under 35 U.S.C. 102

Claims 1-6 were rejected under 35 U.S.C. 102(b) as being anticipated by Prager, U.S. Pat. No. 4,257,416.

In light of the amendments to independent claim 1, it is respectfully submitted that Prager fails to anticipate claims 1-6 under 35 U.S.C. 102(b), as will be hereinafter discussed in detail.

Applicant: Patrice Flaherty
Application No: 10/630,402
Filing Date: 07/30/2003
Attorney Docket No: 1066

Reference is made to MPEP 2131, which states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

It is respectfully submitted that Prager fails to set forth "each and every element as set forth" in amended claim 1, since Prager fails to set forth a device comprising "an indicator unit...having a constant volume...", as set forth in amended claim 1 and defined by claims 2-6 as dependent therefrom.

In contrast, Prager discloses a device comprising an indicator unit (syringe, 45) having a variable volume since the plunger in a syringe is advanced or retracted in a syringe barrel to vary the volume of the syringe during a blood extraction procedure (col. 4, lines 1-4 of the Prager patent).

It is therefore respectfully submitted that Prager fails to anticipate amended claim 1 and claims 2-6 as dependent therefrom under 35 U.S.C. 102(b), under the criteria for anticipation set forth by the Federal Circuit in *Verdegaal Bros. v. Union Oil Co. of California*. Reconsideration and allowance of claims 1-6 is therefore respectfully solicited.

Claim Rejections under 35 U.S.C. 103

Claims 7-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Prager as applied to claims 1-6 above, and further in view of Wilkinson et al. (U.S. Pat. No. 6,235,010).

In light of the amendments to independent claim 7, from which claims 8-11 depend, it is

Applicant: Patrice Flaherty
Application No: 10/630,402
Filing Date: 07/30/2003
Attorney Docket No: 1066

respectfully submitted that claims 7-11 are not rendered obvious by Prager in view of Wilkinson et al. since Prager in view of Wilkinson et al. fails to teach or suggest all of the limitations of amended claim 7, and therefore, claims 8-11 as dependent therefrom.

Reference is made to MPEP 2143.01, which states, "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination". *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Prager discloses a device having a syringe (45) which may be attached to the device to draw blood from a patient through the device (col. 3, line 68 through col. 4, line 6). This is conventionally accomplished using the syringe by increasing the volume of the barrel (indicated by the solid lines in Fig. 1) of the syringe as the syringe plunger (phantom lines) is extended from the barrel. Therefore, Prager teaches the drawing of blood from a patient by vacuum pressure which is induced by increasing the volume of a syringe barrel using a syringe plunger. Referring to Fig. 1 of Prager, in a blood-extraction procedure which is carried out using the Prager device, increasing the volume of the barrel of the syringe (45) would draw air which is initially contained in the tubing segments (16) and (30) into the barrel ahead of the blood as it is drawn from the patient. Therefore, during the blood extraction procedure, the syringe barrel functions as a repository for both air and blood drawn from the tubing segments (16) and (30).

Wilkinson et al. discloses a closed system specimen container (10) having a lid (34) which is fitted with a vent (42). The vent allows air to permeate but prevents liquid to permeate through

Applicant: Patrice Flaherty
Application No: 10/630,402
Filing Date: 07/30/2003
Attorney Docket No: 1066

it (col. 3, line 65).

In the Office action, it was stated, "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination blood collection-fluid administration device as taught by Prager, with Wilkinson since it was known in the art that Wilkinson is used to provide a means for maintaining atmospheric pressure within the device such that no pressure differential exists to hinder fluid transport and in addition to prevent escape or leakage of specimen".

However, it is respectfully submitted that there exists no teaching, suggestion or motivation to provide the air-permeable membrane of Wilkinson on the Prager device. As was set forth herein above, by vacuum pressure, the syringe on the Prager device removes and contains air which is initially present in the tubing segments (16) and (30) of the device at the onset of a blood extraction procedure, due to the increasing volume of the syringe barrel responsive to extraction of the syringe plunger from the barrel. Accordingly, there would be no motivation for a person of ordinary skill in the art to incorporate the air-permeable membrane of Wilkinson into the Prager device such that air in the device could escape from the Prager device and thereby facilitate the free transport of blood in the device during the extraction. In contrast, the syringe of the Prager device performs the function which an air-permeable membrane would otherwise perform if incorporated into the device.

Therefore, it is respectfully submitted that Prager in view of Wilkinson et al. fails to suggest the desirability of incorporating the air-permeable membrane of the Wilkinson et al. device into the Prager device. Accordingly, it is respectfully submitted that Prager in view of Wilkinson et al. fails

NOV-29-05 TUE 9:01 AM JOHN HARRISON

FAX NO. 3187973063
RECEIVED
CENTRAL FAX CENTER

P. 18

Nov 29 2005

Applicant: Patrice Flaherty
Application No: 10/630,402
Filing Date: 07/30/2003
Attorney Docket No: 1066

to teach or suggest all of the limitations of amended claim 7 and claims 8-11 as dependent from amended claim 7 in accordance with the Federal Circuit decision in *In re Mills* (cited hereinabove).

Reconsideration and allowance of claims 7-11 is therefore respectfully solicited.

Conclusion

Every effort has been made to amend applicant's claims in order to define the invention in the scope to which it is entitled. Accordingly, reconsideration and allowance of claims 1-11 and allowance of claims 24-32 is respectfully solicited.

Respectfully submitted,

R. Keith Harrison
R. Keith Harrison
Reg. No. 44,747

November 29, 2005